FDA authorizes Dexcom G6 CGM system

June 2018—The FDA has granted a de novo request to Dexcom for its Dexcom G6 integrated continuous glucose monitoring system for determining blood glucose levels for people with diabetes ages two and older. This CGM system is permitted by the agency to be used as part of an integrated system with other compatible medical devices and electronic interfaces, which may include automated insulin dosing systems, insulin pumps, blood glucose meters, or other electronic devices used for diabetes management. It is designated a moderate risk, class II medical device.

The Dexcom G6 patch device, applied to the skin of the abdomen, contains a small sensor that continuously measures the amount of glucose in body fluid. It transmits real-time glucose readings every five minutes to a compatible display device, such as a mobile medical app, and will trigger an alarm when a patient's blood sugar enters a danger zone. If it is integrated with an automated insulin dosing system, a rise in blood sugar would trigger the release of insulin from the pump. The G6 version is factory calibrated and does not require users to calibrate the sensor with fingerstick blood glucose measurements.

***Dexcom**, 888-738-3646*